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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/649,301	08/27/2003	Mark E. Schnute	01206.US1	5396

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AGOURON PHARMACEUTICALS, INC.  
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EXAMINER
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HUANG, EVELYN MEI

ART UNIT	PAPER NUMBER
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1625

DATE MAILED: 03/31/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No. 10/649,301	Applicant(s) SCHNUTE ET AL.	
	Examiner Evelyn Huang	Art Unit 1625	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 16 December 2004.  
 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.  
 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-36 and 39-48 is/are pending in the application.  
     4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.  
 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.  
 6) ☒ Claim(s) 1-36, 39-48 is/are rejected.  
 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.  
 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.  
 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
     Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
     Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  
 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
     a) ☐ All    b) ☐ Some \* c) ☐ None of:  
         1. ☐ Certified copies of the priority documents have been received.  
         2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
         3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

### **DETAILED ACTION**

1. Claims 1-36, 39-48 are pending. Claims 37, 38, 49 have been canceled according to the amendment filed on 12-16-2004.

#### ***Duplicate Claims***

2. The objection to Claim 38 as being a substantial duplicate of claim 1 is rendered moot by the cancellation of claim 38.

#### ***Claim Rejections - 35 USC § 112***

3. The cancellation of Claim 37 has rendered moot the 35 U.S.C. 112 first paragraph written description rejection and the 112 first paragraph enablement rejection for this claim.

#### ***Claim Rejections - 35 USC § 112***

4. The enablement rejection for Claim 36 under 35 U.S.C. 112, first paragraph is withdrawn because the claim as amended is now commensurate with the scope of the object enablement.

#### ***Claim Rejections - 35 USC § 103***

5. The rejection under 35 U.S.C. 103(a) as being unpatentable over Schnute (6239142, available as prior art under 102(b)) and the rejection under 35 U.S.C. 103(a) as being unpatentable over Schnute (6239142) in view of King are maintained for reasons of record.

Applicants maintain that the generic compound of Schnute does not describe the instant compound in that they have different R4 substituents (corresponding to R3 in Schnute).

On the contrary, Schnute not only generically discloses an anti-herpesviral 4-oxo-4, 7-dihydrothienopyridine carboxamide compound (columns 1-3; column 5, lines 1-2), which encompasses the instant, he also describes specific compounds (column 53, Examples 39, 40;

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column 76, claim 21, compound (5), (6)), which has only one difference from the instant compound. Namely, Schnute's compound has a phenyl whereas the instant has a pyridinyl or pyrimidinyl as R4. Phenyl and pyridinyl are art-recognized isosteric equivalents (King, page 208). Furthermore, Schnute, teaches that phenyl within the meaning of aryl, and quinolinyl, pyridinyl, pyrazinyl or pyrimidinyl within the meaning of heteroaryl are optional choices (column 68, claim 1, lines 1-16; column 5, lines 45-53).

One of ordinary skill in the art would be motivated to replace the phenyl of Schnute's example with the alternative, quinolinyl, pyridinyl, pyrazinyl or pyrimidinyl to arrive at the instant invention with the reasonable expectation of obtaining an additional compound useful for treating herpesviral infection.

Applicants submit that the inventive compounds is more potent than the compounds of Schnute. The phenyl compounds of Examples 39 and 40 of Schnute have an  $IC_{50}$  of 0.31  $\mu M$  (column 28, lines 10-65) whereas the pyridinyl compounds of the instant have an  $IC_{50}$  of 0.06 to 0.20  $\mu M$  (page 29 of the specification, Table 1, Examples 1-5).

However, unexpected results cannot be established because these data are not side by side comparison under the same conditions between the closest compounds. There are no statistical analysis in Schnute or in the instant. Furthermore, the  $IC_{50}$  of 0.31 for Schnute's compounds as recited in the Remarks is actually  $<0.31 \mu M$ , which would embrace the instant 0.06 to 0.20  $\mu M$ .

Since unexpected results have not been established, the instant remains obvious over the prior art of record.

### ***Double Patenting***

6. The rejection for Claims 1-5, 8, 10-14, 21, 25-43 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-21, 23-32 of U.S. Patent No. 6239142 is maintained for reasons of record and for the reasons set forth in paragraph 5 above.

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7. The provisional rejection under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-37 of copending Application No. 10/649202 in view of Schnute (6239142) is maintained for reasons of record.

Applicants contend that the copending compound has a phenyl optionally fused to a pyridinyl whereas the instant has a heteroaryl as R4, and there is no teaching in the present application to substitute a phenyl at R4.

However, Schnute teaches that phenyl within the meaning of aryl, and pyridinyl, pyrazinyl or pyrimidinyl within the meaning of heteroaryl are optional choices (column 68, claim 1, lines 1-16; column 5, lines 45-53). One of ordinary skill in the art would be motivated to replace the copending phenyl with the alternative, pyridinyl, pyrazinyl or pyrimidinyl to arrive at the instant invention with the reasonable expectation of obtaining an additional compound useful for treating herpesviral infection.

The instant quinolinyl as R4 is attached to the N-ethyl via the pyridine ring of the quinolinyl whereas the copending quinolinyl as R4 is bonded to the N-ethyl via the benzene ring of the quinolinyl. The copending compound is therefore a positional isomer of the instant. Schnute, however, teaches that the position of attachment of the heteroaryl is an optional choice (column 70, lines 8-15). One of ordinary skill in the art would be motivated to prepare the positional isomer of the copending compound as taught by Schnute to arrive at the instant invention with the reasonable expectation of obtaining an additional compound useful for treating herpesviral infection.

A timely filed terminal disclaimer would obviate the rejection.

8. The provisional rejection under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-42 of copending Application No. 10/649208 in view of Schnute (6239142) is maintained for reasons of record.

The copending compound has a 5-membered heteroaryl whereas the instant has a 6-membered heteroaryl as R4. Schnute, however, teaches that the 5-membered heteroaryl and the 6-membered heteroaryl are optional choices (column 68, claim 1, lines 1-16; column 5, lines 45-53). One of ordinary skill in the art would be motivated to replace the 5-membered heteroaryl

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with the alternative 6-membered heteroaryl to arrive at the instant invention with the reasonable expectation of obtaining an additional compound useful for treating herpesviral infection.

A timely filed terminal disclaimer would obviate the rejection.

### ***Conclusion***

9. No claims are allowed.

10. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Evelyn Huang whose telephone number is 571-272-0686. The examiner can normally be reached on Tuesday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang can be reached on 571-272-0562. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Evelyn Huang

Primary Examiner

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